

FOREIGN MEDICAL PROGRAM POLICY MANUAL

CHAPTER: 2
SECTION: 4
TITLE: PHARMACY SERVICES, SUPPLIES, AND OVER-THE-COUNTER ITEMS

AUTHORITY: 38 USC 1724, 38 CFR 17.35

I. DEFINITIONS

A. Legend drugs are those that require a prescription by law.

B. Investigational new drugs (IND) are medications for which a new drug application has been filed with the Food and Drug Administration (FDA). An investigational drug may be a new chemical compound, which has not been released by the FDA for general use, or it may be an approved drug that is used for an unapproved or approved use in a controlled, randomized, or blended clinical trial. Investigational drugs usually are not available through commercial channels.

C. Over-the-counter items can include pharmaceuticals, continence-related supplies (catheters, pads, and diapers), and other supplies that are medically appropriate and necessary. Items are used for daily care of patients and are usually obtained from private suppliers such as drug stores, discount stores, or grocery stores.

D. Unlabeled or off labeled drugs or medical devices are those used for indications that are not included in the FDA approved labeling for the condition, diagnosis, or indication.

II. POLICY

A. Drugs and medications, including unlabeled or off labeled use, are covered when all of the following conditions are met:

1. The drug is medically necessary for the treatment of the condition or associated condition for which it is prescribed.
2. The drug is administered according to accepted standards of practice in the VA/US medical community
3. The drug is approved by the FDA for commercial marketing for the specified indication.
4. The drug is prescribed and dispensed in accordance with applicable laws

and licensing requirements,

B. Over-the-counter drugs are covered if medically necessary.

C. Insulin and related supplies may be covered for diabetic patients regardless of whether provided by prescription or over-the-counter.

III. POLICY CONSIDERATIONS

A. Vitamins may be covered only if documentation is submitted showing that it is medically necessary for the treatment of a diagnosed service-connected medical condition.

B. Viagra may be covered for the treatment of organic impotence in males only.

C. Approval for unlabeled or off labeled use may require medical review for appropriateness. If the off labeled or unlabeled use of a drug's safety and effectiveness is questionable, then coverage for the drug will be denied.

D. Parenteral or enteral feedings are covered when medically necessary.

E. Expendable medical supplies required on a recurring basis for home treatment of specific disabilities, such as catheters, incontinence supplies, sheepskins, etc., are covered.

IV. EXCLUSIONS

A. Drugs not approved by the FDA.

B. Placebo injections and drugs are not covered under any circumstances.

C. Drug maintenance programs, when one addictive drug is substituted for another, i.e., coverage of methadone for heroin addiction.

D. The drug is prescribed or furnished by a veteran's family member.

E. Experimental or investigational (unproven) drugs.

F. Items such as bed linens, specialty garments, and clothing.

*** END OF POLICY ***